

Message Text

UNCLASSIFIED

PAGE 01 STATE 073550
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 ISO-00 OES-06 COME-00
L-03 /047 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
ARA/MEX:GFALK(INFO)
EA/EX:EECHAMPAGNE(INFO)
EUR/EX:JLTULL(INFO)

-----031357Z 044275 /41

P 022207Z APR 77

FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY PARIS PRIORITY
AMCONSUL HONG KONG PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY MOSCOW PRIORITY
AMEMBASSY OTTAWA PRIORITY

UNCLAS STATE 073550

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, FR, HK, MX, TH, UR, CA R

SUBJECT: FDA ADVISORY-IMPROPERLY PLATED SKIN ELECTRODES
(T-056-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED:

ELECTRODE LEAD ASSEMBLIES WHICH ARE USED ON BODY SKIN
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 073550

SURFACES WITH LEADS TO ELECTRO-MEDICAL INSTRUMENTS.

PRODUCT IDENTIFICATION:

MANUFACTURING BRAND IS "NCM" AS SHIPPED. 10 OF 11 DIRECT
CONSIGNEES USE THE ASSEMBLIES TO PACK WITH ELECTRO-MEDICAL
INSTRUMENTS AND MAY ALSO DISTRIBUTE THE INDIVIDUAL LEAD

ASSEMBLIES SEPARATELY, POSSIBLY UNDER THEIR OWN BRAND LABELS
(WHICH ARE NOT KNOWN AS PRESENT).

THE ASSEMBLY MODEL (OR PART) NUMBERS WHICH ARE UNDER RECALL
ARE K2088, K2129, K2130, K2298, AND 77009. ALL OF THESE
NUMBERS ARE BEING RECALLED AND WERE MANUFACTURED BY THE
FIRM BETWEEN 10 JUNE AND 31 DECEMBER 1976.

MANUFACTURER/RECALLING FIRM:

NATIONAL CABLE MODELING CORPORATION
136 S. SAN FERNANDO ROAD
LOS ANGELES, CALIFORNIA 90031

THE DEFECTIVE CONTACT DISK THAT WAS USED IN THESE ASSEM-
BLIES WAS CUSTOM SILVER PLATED BY ELECTRONIC SILVER
PLATING SERVICES, 13021 S. BUDLONG, GARDENIA, CALIFORNIA.

2. THE FOLLOWING 11 FIRMS ARE THE TOTAL DIRECT CONSIG-
NEES RECEIVING THIS "SILVER/SILVER CHLORIDE ELECTRODE
LEAD ASSEMBLY". 10 OF THESE FIRMS USE THE ASSEMBLIES
IN THEIR OWN MANUFACTURING OPERATIONS AND ARE SUB-RECALL-
ING.

INSTRUMENTS FOR CARDIAC RESEARCH, INC.
6057 CORPORATE DRIVE, EAST SYRACUSE, NEW YORK 10357

INSTRUMENTATION AND CONTROL SYSTEMS, INC.
125-129 LAURA DRIVE, ADDISON, ILL., 60101
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 073550

RECEIVED 1816 UNITS OF K 2130 (ICS IS 603A0;15/759-00XX).

GOULD STATHAM
3631 PERKINS AVE., CLEVELAND, OHIO 44114
RECEIVED 53 UNITS OF K 2130 (GOULD 283601).

NARCO BIO-SYSTEMS, INC.
7651 AIRPORT BLVD., HOUSTON, TEXAS 77017
RECEIVED 1351 UNITS OF K 2129

BIO-FEEDBACK TECHNOLOGY, INC.
10612 A TRASK AVE, GARDEN GROVE., CA 92643
RECEIVED 868 UNITS ABOUT 50 EACH OF TWO PARTS, NAMELY
K2129 (BIO-FEEDBACK 8224-000)
K2130 (BIO-FEEDBACK 8227-000)

DATASCOPE CORP.,
580 WINTERS AVE., PARAMUS, N.J. 07652
RECEIVED 4042 UNITS OF SK-2088 (DATASCOPE 681-000)

MERCURY ENTERPRISES, INC.
P O BOX DRAWER 20000, ST. PETERSBURG, FLA., 33742
RECEIVED 32 UNITS OF K 2129

AIRSHIELDS, INC.
330 JACKSONVILLE ROAD, HATBORO, PA., 19040
RECEIVED 1416 UNITS OF 77-009-0X

WIGHTMAN MEDICAL INC., (DISTRIBUTOR ONLY)
120 DOYLE STREET, DOYLESTOWN, PA, 18901
RECEIVED 400 UNITS OF K 2129 AND SSK?-?2088 (UNKNOWN)

CUSTOM SYSTEMS ASSOCIATES, INC.
14100 N.W. SCIENCE PARK DRIVE, PORTLAND, OREGON 97229

FOREIGN: QUINTON INSTRUMENTS
UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 073550

- 2250 MIDLAND AVE., UNIT 12, SCARBOROUGH, ONTARIO
- M1P4R9
- RECEIVED 350 UNITS OF K 2129

3. REASON FOR RECALL RECOMMENDATION:

THE BRASS DISK WHICH IS PLATED WITH SILVER FOR CONDUCTIVITY AT AN OUTSIDE FIRM AND THEN RETURNED TO NATIONAL CABLE WHERE THE SILVER CHLORIDE IS COMPOUND ON TO THE DISK FORMING THE "SK-22 SILVER CHLORIDE PELLETT".

THIS PELLETT IS THEN USED IN THE PRODUCTION OF THE LEAD ASSEMBLIES. BECAUSE OF AN INADEQUATE PLATING THICKNESS OF THE SILVER ON THE BRASS DISK THE ZINC FROM THE BRASS REACTED WITH THE SILVER CHLORIDE PRODUCING ZINC CHLORIDE WHICH WAS RESPONSIBLE FOR SKIN IRRITATION AND SKIN BURNS.

4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED LETTER DATED 7 JANUARY 1977 REQUESTING RECALL OF ELECTRODE-LEAD ASSEMBLIES. ALL RECALLS ARE TO BE RETURNED TO NATIONAL CABLE FOR DESTRUCTION. ANY QUESTIONS CONSIGNEES MAY HAVE WITH RESPECT TO RECALL SHOULD BE DIRECTED TO FIRM (NATIONAL CABLE MODELING CORP.)

5. FOREIGN CONSIGNEES AS FOLLOWS:

SDR SCIENTIFIC PTY LTD
P O BOX 45
BALGOWLAH, N.S.W. 2093
AUSTRALIA

ROUCAIRE
20, AV. DE L'EUROPE
B. P. 65
78140 VELIZY
UNCLASSIFIED

UNCLASSIFIED

PAGE 05 STATE 073550

PARIS, FRANCE

ACHELIS (HONG KONG) LIMITED
P O BOX K-9334
KOWLOON CITY, HONG KONG

ESCUELA DE MEDICINA
DE LA UNIVERSIDAD AUTONOMA DE SAN LUIS POTOSI
DEPARTAMENTO DE FISIOLOGIA Y FARMACOLOGIA
AV. V. CARRANZA 2405
APARTDO POSTAL 142
SAN LUIS POTOSI, S.L.P. - MEXICO
ATTN: DR. FEDERICO DIES

TECHNICAL EQUIPMENT COMPANY LTD
100 RAJADAMERN AVE
P O BOX 1175
BANGKOK, THAILAND

NAILMED LTD
NAILMAN HOUSI
2 DENHAM RD
CANVEY ISLAND
ESSEX SS8 9HA
CHAMCON LONDON 88941

V/O MEDEXPORT
G-200
SMOLENSKAJA-SENNAJA 32/34
MOSCOW, USSR
VANCE

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 02-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE073550
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770116-0010
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770494/aaaaddzy.tel
Line Count: 212
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 3e5401ab-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 07-Jan-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2916153
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-IMPROPERLY PLATED SKIN ELECTRODES (T-056-7)
TAGS: OGEN, ETRD, EIND, TBIO, AS, FR, HK, MX, TH, UR, CA
To: CANBERRA PARIS MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/3e5401ab-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009